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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/643,673 | 08/19/2003 | Suong-Hyu Hyon | 1736-000001/REC | 5763 |
| 27572 | 7590 | 06/01/2007 | EXAMINER | |
| HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303 | | | BERMAN, SUSAN W | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1711 | | |
| | | MAIL DATE | | DELIVERY MODE |
| | | 06/01/2007 | | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/643,673 | HYON ET AL. | |
| | Examiner | Art Unit | |
| | Susan W. Berman | 1711 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 December 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 104,109,114,130,135,136,139,144,145,149-168 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 104,109,114,130,135,136,139,144,145 and 149-168 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/06.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/14/2006 has been entered. Applicant's submissions filed 10-16-2006 have been entered as requested in the RCE.

Objection to the Application under 37 CFR 1.172(a)

This application is objected to under 37 CFR 1.172(a) as lacking the written consent of all assignees owning an undivided interest in the patent. The consent of the assignee must be in compliance with 37 CFR 1.172. See MPEP § 1410.01.

A proper assent of the assignee in compliance with 37 CFR 1.172 and 3.73 is required in reply to this Office action.

The paper filed to designate Yoko Gen, C.E.O. of BMG Incorporated, as a person empowered to sign on behalf of the assignee and signed by attorney David L. Suter is accepted. However, the paper "Assignee Consent under 37 C.F.R. 1.172" signed by Yoko Gen as C.E.O. of BMG Incorporated and filed in Application No. 10/141,374 is not accepted in this divisional reissue application. Also, the paper "Statement under 37 CFR 3.73(b) and Power of Attorney or Authorization of Agent filed in Application No 10/141,374 is not accepted in this divisional reissue application. Applicant must submit the required papers in this divisional application.

Oath/Declaration

The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

The oath or declaration is defective because:

It does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing.

Applicant has claimed priority to a Japanese application in the patent file that is not identified in the Reissue Declaration.

The reissue oath/declaration filed with this application is defective because it fails to identify at least one error which is relied upon to support the reissue application. See 37 CFR 1.175(a)(1) and MPEP § 1414. The error set forth in the Declaration filed 08-19-2003 that embodiments focusing on preferred levels of irradiation, i.e. at least about 1 MR, were not specifically claimed is not relevant to the instant claims in this divisional application. The error or errors being corrected in this divisional reissue application must be specifically identified in the Declaration.

In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 104, 109, 114, 130, 135, 136, 139, 144, 145 and 149-168 are rejected as being based upon a defective Reissue Application Declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defects is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

“Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant.”

See MPEP § 1414.01.

Response to Amendments and Remarks

The rejections under 35 USC 112, first and second paragraphs, set forth in the Final Office Action are withdrawn in response to the amended claims.

The rejections of some of the claims under 35 U.S.C. 102(b) as being anticipated by or under 35 U.S.C. 103(a) as obvious over Sun et al (5,414,049) are withdrawn in response to the amended claims and Remarks.

Applicant argues that the scope of the phrase “raw UHMWPE article” is the same as the phrase “article comprising UHMWPE”. This argument is not persuasive because the article “comprising” UHMWPE can contain materials or parts of an article other than UHMWPE, whereas the phrase “raw UHMWPE article” is considered to set forth an article made of raw UHMWPE. It is not agreed that the phrase “raw UHMWPE article” encompasses UHMWPE including antioxidants, lubricants, pigments or other additives. The only definition of “raw UHMWPE” found in the specification is that the weight-average molecular weight of the polyethylene is from 2 to 8 million and the melting point is approximately 136⁰ to 139⁰ C in column 3, lines 21-26.

Rejection under 35 U.S.C. 251

Claims 104, 109, 114, 130, 135, 136, 139, 144, 145 and 149-168 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Pannu v. Storz Instruments Inc.*, 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001); *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to claim subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope of claim subject matter surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

The following subject matter appears to be an attempt to recapture subject matter surrendered during prosecution of the parent application:

The amendments cited below were made during prosecution in parent application Serial No. 08/640,738, which issued as Patent 6,168,626.

The recitation “article” in claims 104, 114, 130 and 139 is a broader than the recitation of a “molded article” set forth in the original claims. In Amendment B, filed 04-02-1997, the phrase “molded article” was amended to set forth a **“molded article having orientation of crystal planes”** in order to distinguish over Rosenzweig, US 5,030,487. The present term “article” is broader in scope than the phrase “molded article” or the phrase “molded article having

orientation of crystal planes". The phrase "molded article having orientation of crystal planes" was further amended to read "molded article having orientation of crystal planes **in a direction parallel to a compression plane**" in the Amendment C, filed 12/5/1997, in order to distinguish over cited Patent 4,655,769 to Zachariades. The present term UHNWPE "article" is a broadening of the amended claim language wherein "molded article" was changed to read "**molded block**" in Amendment F filed 02-25-1999 in order to distinguish over Patent 3,886,056 to Kitamaru et al. In summary, the method claims in the parent application were limited to read an UHMWPE "**molded block having orientation of crystal planes in a direction parallel to a compression plane**" in order to distinguish over the prior art cited during prosecution.

With respect to step (a) in the instantly claimed method, Applicant added the limitation "**having a molecular weight not less than 5 million**" to define the UHMWPE molded block in the step of slightly crosslinking an UHMWPE molded block by irradiating the block with a high energy ray. This limitation was added in Amendment H filed 05-04-2000 in order to distinguish over Kitamaru et al.

With respect to step © in the instantly claimed method, the instant claims are broadened by failing to recite that the molded article is made by compression deforming the heated article "**by compressing the block in a direction perpendicular to a compression plane so as to deform the block**". This limitation was added in Amendment D filed 09-03-1998 in order to resolve the rejection under 35 US 112, second paragraph, that the phrase "orientation of crystal planes in a direction parallel to a compression plane" discussed above was indefinite when the orientation of the compression plane was not defined.

With respect to step (d) in the instantly claimed method, the instant claims do not recite the limitation "**said block after cooling having a thickness range of 5 to 10 mm in a direction**

perpendicular to the compression plane". Amendment G filed 09-10-1999 introduced this limitation to distinguish the "molded block" recitation from the films and sheets disclosed by Kitamura et al..

With respect to step (d), Amendment G filed 09-10-1999 also introduced the limitation "**under pressure**" to the phrase "keeping the block in a deformed state under pressure" in order to distinguish over the process taught by Kitamura et al.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 104, 109, 114, 149-152 and 154-157 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitamaru et al (3,886,056). Kitamaru et al disclose a process for irradiating polyethylene, including polyethylene preferably having a molecular weight from 2×10^5 to 1×10^6 and 4×10^6 , with ionizing radiation to produce crosslinked polyethylene having a gel content of at least one weight percent (column 1, line 65, to column 2, line 50). Low dose irradiation is taught in column 3, lines 1-11. A process comprising heating to a molten state, extending the polyethylene under increased pressure, and cooling the article while the extended dimension is maintained is taught in column 3, lines 13- 45. Irradiation followed by compression at 180°C followed by cooling and orientation of crystal planes in a direction parallel to the compression plane is disclosed in Examples 1-3. With respect to claims 150 and 152, polyethylene having a

molecular weight 4×10^6 and dosages from 0.2 to 16 Mrads are taught in column 3, lines 1-10. With respect to claims 151 and 156, the product produced by the process taught by Kitamaru et al would be expected to include an irradiation product having 0.1 to 10 crosslinking points per 1 molecular chain because the disclosed process meets the requirement of the instantly claimed process and thus would be expected to inherently provide the same properties to the product produced.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 104, 109, 114, 130, 135, 136, 139, 144, 145 and 149-168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitamaru et al, as applied to claims 104, 109, 114, 149-152 and 154-157 above, and further in view of Zachariades (5,030,402). Kitamaru et al do not teach the instantly claimed step (d) of heating to a temperature from 100°C to 130°C after applying pressure in step (c) or the instantly claimed step (f) of processing the article to make a component for an artificial joint.

Zachariades teaches compression deformation of oriented UHMWPE to obtain enhanced properties. Compression molding at between 80°C and the melting temperature of the polymer, preferably between 100°C and 130°C , and shaping into a final product is taught in column 3,

lines 25-44. Zachariades also teaches maintaining pressure after cooling to ambient temperature to aid in retaining the attained chain orientation (column 4, lines 1-11).

It would have been obvious to one skilled in the art at the time of the invention to employ the compression-deformation process for orienting and extending UHMWPE taught by Zachariades in the extending step for orienting and extending polyethylene disclosed by Kitamaru et al. Kitamaru et al provide motivation by teaching that the crosslinked polyethylene should be extended in a molten state. Zachariades provides motivation by teaching that enhanced properties can be obtained by compression at the temperatures taught. One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of obtaining enhanced mechanical properties, as taught by Zachariades.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 104, 109, 114, 130, 135, 136, 139, 144, 145 and 149-168 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 104-111, 114-119, 122-127, 130-136 ,139-145 of copending Application No. 11/522,504. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method set forth in the instant claims includes the same steps set forth in the claims of A.N. 11/522,504.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W. Berman whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seedless can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB
1/22/07



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